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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

24265 7590 11/20/2006

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/10/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9 and 17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, and 17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2006 has been entered.

2. Applicant's amendments, filed 09/18/2006 and 10/10/2006, have been entered.

Claims 1-6, 8, and 10-16 have been canceled.

Claims 7 and 9 have been amended.

Claims 7, 9, and 17-30 are pending and currently under consideration as they read on a purified antibody or fragment thereof specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:6.

3. This Office Action is in response to Applicant's amendment to the claims and remarks filed 10/10/2006.

The rejections of record can be found in the previous Office Actions, mailed 2/22/2006 and 7/17/2006.

4. The prior rejection under 35 U.S.C. § 112, 2nd paragraph regarding claim 9 has been withdrawn in view of Applicant's amended claims filed April 14, 2006.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18, 24, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in the previous Office Actions.

A) Claim 18 is indefinite in the recitation of "antibody half molecule" because the phrase fails to point out and distinctly claim the subject matter of the claimed invention with identifying characteristics.

Applicant's arguments have been fully considered but have not been found convincing, essentially for the reasons of record put forth in the prior Office Actions.

Applicant argues that "antibody half molecule" is defined as a structure that contains one antibody heavy chain and one antibody light chain in US Patent 4, 470,925; thus one of ordinary skill in the art would have understood the meaning of the term.

This is not found persuasive. Applicant has not point out the support for the claimed "antibody half molecule" in the instant specification. It is noted that during patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. See MPEP 2173.04.

Therefore, "antibody half molecule" when given the broadest reasonable interpretation would encompass any half of an antibody e.g. the half antibody molecule comprising only the Fc region. Thus the phrase fails to point out and distinctly claim the subject matter of the claimed invention with identifying characteristics.

B) Claims 24 and 30 are indefinite in the recitation of "a unit dose" because the metes and bounds of the "unit dose" are unclear and ambiguous. It is not clear what "a unit dose" encompasses and one of ordinary skill in the art would not be reasonable apprised of the metes and bounds of the invention.

Applicant's arguments have been fully considered but have not been found convincing, essentially for the reasons of record put forth in the prior Office Actions.

Applicant argues that one skilled artisan would have understood that in a unit dose, medication is dispensed in a package that is ready to administer to a patient.

This is not found persuasive because the metes and bounds of "a unit dose" is unclear and ambiguous. The term is not defined by the specification and one ordinary skill in the art would not be reasonable apprised of the metes and bounds (e.g. dosage of the active ingredient) of the claimed "a unit dose".

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 7, 9, and 17-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) (see entire document) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) for reasons of record set forth in the previous Office Actions.

Applicant's arguments have been fully considered but have not been found convincing, essentially for the reasons of record put forth in the prior Office Actions.

Applicant argues that claim 7 has been amended to recite "wherein when said antibody or fragment thereof is contacted with a sample suspected to contain the polypeptide o f SEQ ID NO:6 under conditions in which a stable antigen-antibody complex can form between said antibody or fragment thereof and said polypeptide in said sample, any antigen-antibody complex formation is detected, wherein detection of an antigen-antibody complex indicates the presence of the polypeptide of SEQ ID NO: in said sample". Therefore, claim 7 as amended, are drawn to an antibody or fragment thereof specifically binds the polypeptide of SEQ ID NO:6, but not specifically bind other antigens because antigen-antibody complex formation indicates specific binding between antigen and antibody; thus exclude the referenced antibody taught by Adema et al.

This is not found persuasive for following reasons:

Contrary to applicant's arguments, the polypeptide having the amino acid sequences of SEQ ID NO:2 taught by Adema et al. is 80.4% identical to the claimed polypeptide of SEQ ID NO:6. Adema et al. teach methods of making and using antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology.

Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers and be presented in unit dosage form for parenteral administrations (e.g. see page 4 and 22-45).

In addition, the teachings of Bost et al. and Bendayan provide technical reasoning to support the determination that antibody binding of distinct proteins was indeed specific. For example, Bost et al. teach antibodies against the HIV envelope peptide also cross-react with IL-2 by forming a stable antigen-antibody complex; in fact there is no significant difference between the ability of anti-HIV antibody and anti-IL-2 antibody to recognize IL-2 (see entire document, particularly Results on pages 579-583).

Further, it is noted that the arguments of counsel cannot take the place of evidence in the record. See MPEP 716.01(c).

Here given the high degree of homology between the claimed SEQ ID NO:6 and the reference polypeptide, the referenced antibody would bind the claimed SEQ ID NO:6 and form a stable antigen-antibody complex.

Therefore the prior art antibodies anticipate the claimed invention.

The rejection or record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein as if reiterated in full.

7. *No claim is allowed.*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
November 8, 2006

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
11/8/06